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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/459,522	12/13/1999	CHET M. CRUMP	041861-01500	1246
23556	7590	07/01/2003		
KIMBERLY-CLARK WORLDWIDE, INC. 401 NORTH LAKE STREET NEENAH, WI 54956			EXAMINER	
			EREZO, DARWIN P	
ART UNIT	PAPER NUMBER			
3761				
DATE MAILED: 07/01/2003				

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/459,522	CRUMP ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Darwin P. Erez	3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 April 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 18 is/are allowed.
- 6) Claim(s) 1-17 and 19-25 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                               | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)           | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ .                                   |

**DETAILED ACTION*****Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-17, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,582,161 to Kee in view of US 5,343,857 to Schneider et al.

3. **As to claim 1**, Kee teaches an apparatus comprising a catheter **30**; a manifold **10**; and a valve **20** disposed in the manifold, the valve being configured to selectively limit the withdrawal of air from the ventilation circuit , wherein the valve is capable of being opened by the catheter (as seen in Fig. 1); and wherein the valve is a flap. Kee is silent with regards to the valve having at least one protrusion. Schneider teaches a valve **16** for a catheter manifold, wherein the valve comprises protrusions (at the distal end of the valve flap **20**); and wherein the design of this valve with protrusions helps maintain the valve in a closed position. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to change the valve of Kee to that of Schneider because Schneider discloses that the design of his valve (having protrusions) helps assist in keeping the valve closed whenever pressure within the manifold is greater than atmospheric pressure (col. 5, lines 31-40 of Schneider et al.).

4. **As to claim 2**, Schneider discloses a valve comprising a flap **20** movable between a fist, distal position (see Fig. 4), and a second, proximal position (see Fig. 2).

5. **As to claim 3,** Schneider teaches the flap having a protrusion engaging the catheter.
6. **As to claim 4,** Schneider teaches a catch **19** to engage the flap as is drawn into the second, proximal position, and to retain the flap in the second position (member **19** engages flap **20**, as seen in Fig. 2, and retains flap **20** in the closed, second position).
7. **As to claim 5,** Schneider teaches a flap **20** that is pivotably connected to the manifold.
8. **As to claim 6,** Schneider teaches a valve having a flap that is generally disk-shaped because the valve is located within port **15**, which is circular.
9. **As to claim 7,** Schneider teaches a valve having an open position (as seen in Fig. 4) and a closed position (as seen in Fig. 2) wherein friction maintains the valve in the closed position.
10. **As to claim 8,** Schneider teaches a valve comprising an aperture (as seen in Figure 4, where the catheter **23** passes through) and the flap disposed to selectively cover the aperture.
11. **As to claims 9 and 10,** Kee is silent with regards to the manifold comprising a collar. Schneider teaches a collar **33** having a port for injecting fluids. Therefore, it would have been obvious to one of ordinary skill in the art to add the collar of Schneider to that of Kee because it allows a user to inject fluids into the manifold to clean the suction catheter (col. 6, lines 24-32).
12. **Claims 11 and 12** are equivalent in scope to claim 1, as discussed above, and are included with the combination of Kee/Schneider.

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13. **As to claims 13 and 14,** Kee teaches a wiper seal **31** but is silent with regards to the device having a second wiper seal. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add a second wiper seal since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

14. **As to claim 15,** Kee teaches an apparatus comprising a catheter **30**; a protective sheath **12**; a manifold **10**; and a valve **20** disposed in the manifold, the valve being configured to selectively limit the withdrawal of air from the ventilation circuit , wherein the valve is capable of being opened by the catheter (as seen in Fig. 1); and wherein the valve is a flap. Kee is silent with regards to the valve having at least one protrusion. Schneider teaches a valve **16** for a catheter manifold, wherein the valve comprises protrusions (at the distal end of the valve flap **20**); and wherein the design of this valve with protrusions helps maintain the valve in a closed position. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to change the valve of Kee to that of Schneider because Schneider discloses that the design of his valve (having protrusions) helps assist in keeping the valve closed whenever pressure within the manifold is greater than atmospheric pressure (col. 5, lines 31-40 of Schneider et al.).

15. **As to claim 16,** Schneider teaches a valve comprising a pivotable flap **20**.

16. **As to claim 17,** Schneider teaches a valve comprising an aperture (as seen in Figure 4, where the catheter **23** passes through).

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17. **As to claims 19 and 20**, Schneider teaches a locking member **19** disposed in communication with the flap **20** for selectively preventing movement of the flap (as seen in Fig. 2, member **19** engages flap **20** and prevents further movement inwardly) and wherein the locking member comprises a projection extending inwardly.

18. Claims 21-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kee in view of Schneider et al. and in further view of US 6,168,758 to Forsberg et al.

19. **As to claims 22-25**, Kee/Schneider fails to specifically teach the type of material the valve is constructed of. Forsberg et al. discloses a liquid assay device comprising a valve composed of polyether block amides (col. 6, lines 38-49). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use any well known material, including the polyether block amides of Forsberg et al. or the recited limitations of the claims, because it is a mere substitution of one valve material for another. Also, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of choice. *Sinclair & Carroll Co. V. Interchemical Corp.*, 327, 65 USPQ 297 (1945) also note *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960).

***Allowable Subject Matter***

20. Claim 18 is allowed.

***Response to Arguments***

21. Applicant's arguments filed 4/10/03 have been fully considered but they are not persuasive.

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22. In response to Applicant's arguments that Kee fails to teach a flap that is opened by the catheter, it should be noted that Kee does teaches a flap that is opened by the catheter assembly 11. The claims as recited merely states that the flap valve is opened by the catheter but does not recite how it's opened by the catheter. Therefore, Kee teaches a flap valve that is opened by the catheter in conjunction with an adaptor since the applicant has not limited the claim to a flap valve being directly opened by the surface of the catheter itself.

***Conclusion***

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezo whose telephone number is (703) 605-0420. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

dpe  
June 23, 2003

  
WEILUN LO  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 3700